FBI Laboratory Practices for Writing Technical Procedures

1 Purpose

Technical procedures will be used for all processes for which they exist and are applicable. Technical procedures should conform to accepted consensus standards, where applicable. These practices specify the required elements for preparing a technical procedure and when a technical procedure is needed. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who prepare technical procedures, as described in the FBI Laboratory Operations Manual (LOM) - Practices for Document Control, that have a direct effect on the quality of examinations and DNA databasing.

3 Practices

The Technical Leader will ensure a discipline and/or category(ies) of testing has technical procedures where required and the technical procedures are appropriate for use. The Unit Chief will ensure the personnel in their unit follow the appropriate technical procedures.

3.1 Applicability

Processes for which technical procedures are required are as follows:

- Examination and DNA databasing.
- Sampling, when not included in an examination procedure.
- Operation of equipment, when not included in an examination procedure or when manufacturers' procedures do not exist or are not used.
- Database searches when related to examinations.

3.2 Content Detail

Each technical procedure must:

- Be clear, precise, and comprehensive.
- Use language and detail appropriate to performing the tasks described.
- Be written in a manner that clearly describes the steps and ensures ease of use.
- Have adequate detail to preclude misinterpretation.
- Permit a person with an appropriate background in the science, discipline, and/or category of testing to independently perform the same procedure and obtain comparable results.

3.3 Format

The following sections are required in each technical procedure. If the section is addressed in a separate technical procedure, the title of the separate technical procedure will be referenced. If the section does not pertain to a procedure, the phrase "not applicable" will be listed under the section heading. Additional sections may be included for a particular technical procedure, as necessary. Sections may appear in any order.

3.3.1 Title

Titles used in technical procedures should be brief and easily associated to the content.

3.3.2 Scope

The scope will specify the applicability of the procedure to include to whom it applies.

3.3.3 Equipment/Materials/Reagents

This section will list pertinent equipment, materials, reagents, working standards, controls, reference materials, and/or reference standards used in performing the procedure. Each item should be specified to ensure the proper item of the appropriate quality is identified.

3.3.4 Standards and Controls

This section will provide instructions for preparing and/or checking standards and controls, including criteria for acceptance or rejection of data based on results for standards and controls.

3.3.5 Sampling

This section will include information on sampling as described in the QAM – Section 7.3.

3.3.6 Procedure

This section will specify the steps required to perform the procedure. This section may include the use of controls, standards, and blanks; instructions for performance checks; and/or precautions to be taken to minimize contamination and/or degradation.

3.3.7 Calculations

This section will provide example calculations used for statistical or other evaluation of data. This may include criteria for acceptance or rejection of data based on results for controls, standards, blanks, or other quality control checks.

3.3.8 Measurement Uncertainty

This section will detail how measurement uncertainty was determined and will be reported.

3.3.9 Limitations

This section will specify under what circumstances, including environmental conditions, the procedure may not provide accurate results, when it should not be used, and any other limitations specific to the procedure.

3.3.10 Safety

This section will document hazards associated with performing the procedure. See the FBI Laboratory Safety Manual.

3.3.11 References

This section will identify documents used in developing a technical procedure or sources for further information. References may include relevant national or international standards and technical publications, operating manuals supplied by an equipment manufacturer, relevant technical documents, and established in-house methods.

3.3.12 Approval

This section will contain approvals according to the LOM – Practices for Document Control.

4 Records

Records generated and/or retained by these practices will be specified in the LOM - Practices for Document Control.

5 References

<u>FBI Laboratory Operations Manual</u>, Practices for Document Control, Federal Bureau of Investigation, Laboratory Division, latest revision.

<u>FBI Laboratory Quality Assurance Manual</u>, Federal Bureau of Investigation, Laboratory Division, latest revision.

<u>FBI Laboratory Safety Manual</u>, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual Writing Technical Procedures Issue Date: 12/21/2020 Revision: 9 Page 4 of 5

<u>ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration</u> <u>Laboratories</u>, International Organization for Standardization, Geneva, Switzerland, 2017.

<u>ISO/IEC 17020 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection,</u> International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

FBI Laboratory Operations Manual Writing Technical Procedures Issue Date: 12/21/2020 Revision: 9 Page 5 of 5

 Rev. #	Issue Date	History
 8	06/03/19	Updated section 3.3.5 on sampling and adding reference to QAM
		7.6 in section 3.3.8. Updated list of references in section 5.
9	12/21/20	Grammatical and editing changes made throughout for clarity
		Replaced: SOPs with technical procedures throughout
		Replaced: casework with examinations throughout
		5 – Added: FBI Laboratory Safety Manual and ISO/IEC 17020

Redacted - Signatures on File

Approval

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020